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No. : 03-1175

Supreme Court, U.S.
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In the

Supreme Court of the United States

VALLEY DRUG COMPANY,
LOUISIANA WHOLESALE DRUG COMPANY, INC.,
Petitioners,

-against-

GENEVA PHARMACEUTICALS, INC.,
ABBOTT LABORATORIES,
Respondents.

REPLY TO BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

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CORPORATE DISCLOSURE STATEMENT

Petitioners' Corporate Disclosure Statement was set forth at page ii of their Petition for a Writ of Certiorari, and there are no amendments to that Statement.

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ARGUMENT

Respondents concede that there is a circuit split as to whether it is a *per se* violation of Section 1 of the Sherman Act for a patent holder to pay its competitors not to compete during the pendency of a patent challenge. They also concede that the issue is extremely important. Resp. Bf. at 8. Respondents even advocate that the Court *grant certioriari* in this case if the Court seeks to resolve the circuit split in an analogous case, *Louisiana Wholesale Drug Co. v. Hoechst Marion Roussel, Inc.*, 332 F.3d 896 (6th Cir.), *petition for cert. filed sub nom. Andrx Pharm., Inc. v. The Kroger Co.*, No. 03-779 (November 21, 2003) ("*Andrx*"). Resp. Bf. at 7-8. Nevertheless, Respondents contend, absent the Court's review of *Andrx*, the Court should delay resolving this important antitrust issue splitting the circuit because: (a) the split exists "between just two circuits", and (b) the petition seeks interlocutory review of an order that may be mooted by summary judgment motion. As detailed below, Respondents' arguments are all without merit. Immediate review is necessary to resolve the Circuit split regarding this important antitrust issue that could impact generic competition for brand-name drugs with annual sales of more than $20 billion.

I. There is No Reason to Prolong the Circuit Split In Order to Allow Other Courts to Decide the Issue.

a. Market Allocation Agreements Have Been Per Se Illegal For Decades

Respondents urge the Court to delay review of the issue presented because Petitioners "seek expansion of the Per Se Rule to a type of restraint with which the courts are just beginning to gain experience." Resp. Bf. at p. 8. Respondents'

argument is flawed because it improperly focuses on the Court's experience with this type of agreement in the pharmaceutical *industry*. Whether the courts have long experience with a particular industry is irrelevant to the inquiry; what matters is whether the *type of restraint* is one that the Supreme Court has condemned as *per se* unlawful. *Arizona v. Maricopa*, 457 U.S. at 350-51 & n. 19.

Here, as the Sixth Circuit found in *Andrx*, the Agreement constitutes an express, naked horizontal territorial restraint that has long been held *per se* illegal under Section 1 of the Sherman Act.[1] It has been illegal *per se* for over a century for actual or potential competitors to allocate markets among themselves. *See, e.g., U.S. v. Addyston Pipe & Steel Co.*, 85 F. 271, 293-94 (6th Cir. 1898), *aff'd* 179 U.S. 211 (1899); *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49-50 (1990); *U.S. v. Topco Assoc. Inc.*, 405 U.S. 596, 608 (1972). Such agreements have "such predictable and pernicious anticompetitive effects" that, absent efficiency-enhancing

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[1]As explained in the Petition, under the challenged agreement, Geneva agreed that in exchange for Abbott's promise to pay it $4.5 million per month, Geneva would "not sell, offer for sale, donate or otherwise distribute in the United States any Terazosin Hydrochloride Product...." The Agreement did not settle the patent litigation between Abbott and Geneva. Rather, under the Agreement, Geneva was to stay off the market until: (a) another patent owned by Abbott but not the subject of the pending litigation between Abbott and Geneva (U.S. Patent No. 4,251,532) expired (in February 17, 2000); (b) another generic version of Hytrin had entered the market; or (c) a final, unappealable judgment had been rendered in the patent infringement suit brought by Abbott against Geneva's generic, tablet version of Hytrin, whichever occurred first. The latter condition required a final judgment from which no further appeal could be taken, including resolution of any petition for certiorari to this Court. Pet. App. 113a-114a.

economic activity, they are *conclusively presumed* to be anticompetitive, thereby obviating the need for a complex, expensive and time consuming analysis of the agreement's anticompetitive and (supposedly) procompetitive effects under the rule of reason. *Arizona v. Maricopa County Medical Society*, 457 U.S. 332 (1982).

The fact that the parties to the Agreement were involved in litigation involving Abbott's patent does not change this conclusion. Abbott's payment to Geneva bolstered its *possible* ability *to exclude* competitors (by meeting the strict requirements for obtaining a preliminary injunction or threatening to obtain damages in the infringement suit) into an *absolute, guaranteed* power to exclude. The Sixth Circuit in *Andrx* recognized that the payment *guaranteed* to the patent holder that its only generic competitor would not come to market and held "it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market." Thus, the Sixth Circuit, unlike the Eleventh Circuit, recognized that *guaranteed* exclusion of a competitor through the payment of money to refrain from competition is greater than the exclusionary effect of the patent alone.

It has been settled law for decades that when the patent owner exercises exclusionary power beyond that conferred by the patent, it and its coconspirators are fully subject to the antitrust law, including the *per se* rule. *See, e.g., United States v. New Wrinkle, Inc.*, 342 U.S. 371, 377-80 (1952) (patent pooling agreement fixing the prices at which licensees would sell patented products was beyond the patent monopoly and held per se illegal); *United States v. Line Material Co.*, 333 U.S. 287, 314 (1948) (price-fixing pursuant to patent cross-licenses

per se illegal since this is more than exploitation of patents); *United States v. Masonite Corp.*, 316 U.S. 265, 282 (1942) (price-fixing by patentee and competitors through agency agreements constituted an enlargement of the limited patent grant and was therefore per se illegal).[2]

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[2]Respondents also contend that "it is Congress' and the FDA's considered judgment that it is pro-competitive to delay generic marketing, as the Petitions allege the parties did here, pending resolution of the patent disputes." Presumably, Respondents are invoking Congress' grant to patent holders in the Hatch-Waxman Act of thirty months of guaranteed exclusion pending resolution of a lawsuit initiated by the patent holder. 21 U.S.C. § 355(j)(5)(B)(iii). Surely, however, the statute cannot be read as giving patent holders *carte blanche* to exclude generic competition indefinitely and without properly invoking the procedures described in the Hatch-Waxman Act. Indeed, the automatic exclusion – which in original versions of the legislation was for only eighteen months – was part of the complex balancing by Congress between the rights of patent holders and those of consumers and generic manufacturers. *See* Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389, 398-407 (1999) (reviewing legislative history). Here, Abbott failed to invoke the Hatch-Waxman 30 month stay by failing to bring a timely suit regarding Geneva's generic capsule. Hence, Abbott was not entitled to exclude Geneva (prior to a determination on the merits) other than by obtaining a preliminary injunction. And, they were not entitled to extend by agreement the 30 month exclusivity for tablet version. Hatch-Waxman affirmatively gives generics the right to come to market after 30 months even if the patent suit is not resolved. Indeed, many generic companies (including Geneva) have come to market prior to the resolution of patent suits. *See, e.g.*, http://www.novartis.com/downloads/novartis1qresults _2002.pdf at p. 6 (notes launch of generic Relafen in February 2002 despite ongoing patent litigation); *SmithKline Beecham v. Copley Pharm. Corp.*, 2002 WL 1890708 (Fed. Cir. Aug. 15, 2002) (decision six months after Geneva launched affirming district court finding of invalidity of Relafen patent in consolidated case in which Geneva was a party); http://www.novartis.com/annual_reports/2002/en/fin_rep/notes19c.shtml. (Geneva launched generic version of Augmentin after May 2002 district court decision; notes GlaxoSmithKline has appealed the ruling)).

There is simply no merit to the argument that the Court needs more time to gain experience with this type of restraint before granting certiorari to resolve the issue.

b. The Circuit Split Between the Sixth and Eleventh Circuit is Having a National Effect

Respondents contend that review is improper because "[t]he Petitions identify a split in just two circuits". Resp. Bf. at 10. However, Respondents' argument ignores the importance of the issue Petitioner asks the court to review for its impact on antitrust jurisprudence and on competition between brand name and generic drugs. *See, e.g., Alaska Dep't of Conservation v. Environmental Protection Agency,* 124 U.S. 983, 998 *(2004)* (granting certiorari "to resolve an important issue of federal law."); *Pharm. Research and Mfrs of Am. v. Walsh,* 538 U.S. 644, 650 (2003) ("we granted certiorari because the questions presented are of national importance."

Moreover, Respondents ignore the national impact the split in circuits on this important federal antitrust issue is having. Currently before the Eleventh Circuit is the FTC's decision rendered in *In re Schering-Plough Corp.*, No. 9297, Comm'n Op., 2003 WL 22989651 (FTC Dec. 18, 2003). In *Schering*, the FTC held that the substantial reverse payment made by the patent holder to its generic competitor was anticompetitive. *Id.*[3] The FTC stated that a substantial reverse

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[3]As the FTC explained:

The payment is characterized as "reverse" because it flows from the pioneer to the generic, unlike the more

payment raises a "red flag" and in future cases involving such payments the Commission may apply a "more truncated" analysis. *Id* at 16. The FTC proposed that if complaint counsel have made out a *prima facie* case that the agreement has anticompetitive effects, the burden is on defendants to demonstrate that the challenged provisions are justified by procompetitive benefits that are "both cognizable and plausible." *Id.* at 9.[4] Under 15 U.S.C. § 45(c), which allows an appeal from an order from the FTC to any circuit where the challenged practice was used or corporation carries in business, Defendants in *Schering* could appeal the FTC's order in any Circuit Court of Appeals. Not surprisingly, they chose the Eleventh Circuit.[5] Left unaddressed, the Eleventh Circuit's opinion and analysis could legitimize the use of similar non-competition agreements to halt the imminent competition of generic competition for brand-name drugs with annual sales of more than $20 billion and the consumer benefit that it promises.

> common provisions of a patent litigation settlement where the alleged infringer pays royalties to the patent holder in exchange for a license.

Id. at 44 n. 9.

[4] The FTC does not prohibit a payment by the pioneer to the generic that is limited to litigation costs up to $2 million if the Commission has been notified of the settlement. *Id.* at 9. Here, Abbott's agreement to pay Geneva $4.5 million *per month* not to compete with Hytrin exceeds the FTC's $2 million litigation cost exception.

[5] The FTC's decision itself also demonstrates that this issue is currently ripe for review. This Court relies on the FTC for its expert views of the antitrust laws. *See FTC v. Cement Inst.*, 333 U.S. 683, 720 (1948). The FTC noted the split in the Circuits, that the issue will recur and that its decision "would have an impact not only on this particular case but also on other antitrust cases before the commission and the courts that involve the legality of patent settlements."

66 Fed. Reg. 12512, 12513 (2001).[6]

II. Resolution of the Issue Should Not Await Further Proceedings in the District Court

Respondents argue that granting certiorari to review an interlocutory order is generally inappropriate. However, where the lower court's opinion has decided an important issue that is otherwise worthy of review, the interlocutory status of the order will not be an impediment to certiorari. *See* Robert L. Stern *et al.*, Supreme Court Practice § 4. 18 at 260 (8th ed. 2002) (citing cases). Whether it is a *per se* violation of Section 1 of the Sherman Act for a patent holder to pay its competitors not to compete during the pendency of a patent challenge is such an issue. Indeed, this Court has granted interlocutory review to determine whether the *per se* rule should govern in other instances. *See, e.g., Arizona v. Maricopa County Med. Soc'y*, 457 U.S. 332, 336-337 (1982); *Catalano, Inc. v. Target Sales, Inc.*, 446 U.S. 643, 643-644 (1980).

Additionally, the court should give weight to the fact that permission to take an interlocutory appeal from the district court's order under Interlocutory Appeals Act of 1958, 28 U.S.C. § 1292(b) was granted by the Eleventh Circuit. Indeed, as a leading Supreme Court practice commentator points out:

> [T]he Act by its reference to such factors as 'a controlling question of law as to which there is a substantial ground for difference of opinion

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[6]Likewise, plaintiffs in antitrust suits may sue "in any district wherein [the defendant] may be found or transacts business" 15 U.S.C. § 22. Left unaddressed, the circuit split may result in an onslaught of cases by plaintiffs seeking antitrust damages from companies that do business throughout the country in the district courts within the Sixth Circuit.

> and the material advancement of 'the ultimate termination of the litigation' incorporate some of the considerations relevant to the Court in deciding whether to review any nonfinal judgment.[7]

See Robert L. Stern *et al.*, Supreme Court Practice § 4. 19 at 261 (8th ed. 2002).

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[7]Respondents incorrectly contend that certain causation defenses that they are positing in a summary judgment motion would "[i]f successful"... "moot the antitrust liability issues raised by the petition." Resp. Bf. at 13.As an initial matter, plaintiff believes that respondents' summary judgment motion is without merit and will be overcome. Regardless, even if summary judgment on the causation issue were granted, that would impact Petitioner's Clayton Act claim, but it would not moot the issue of whether Respondents engaged in illegal conduct under the Sherman Act.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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